

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Judith A. Varner

Serial No.: 09/307,223

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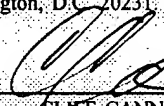
Entitled: **METHODS FOR DETECTING AND  
INHIBITING ANGIOGENESIS**

Group No.: 1642

Examiner: S. Ungar

**DECLARATION OF DR. VIRGIL L. WOODS, JR.  
UNDER 37 C.F.R. §1.132**

Assistant Commissioner for Patents  
Washington, D.C. 20231

<b>CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)</b>	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
Dated: <u>February 19, 2002</u>	By:  CLIFF CANNON-CIN

Sir:

1. I, Dr. Virgil L. Woods, am the subject of the attached Curriculum Vitae and author of the publications shown on the list attached thereto. On the basis of the information and facts contained in these documents, I submit that I have been, and am, practicing in the field of integrin biology and biochemistry, and am qualified to speak on the level of ordinary skill in these fields.

2. I have read and understand the above-identified patent application, and pending claims as amended in the Amendment And Response which was mailed to the Office on September 5, 2001.

3. Claim 2 recites an agent which "does not substantially interfere with the specific binding of a ligand to an integrin other than  $\alpha 5 \beta 1$  integrin to its ligand."

4. The Specification teaches that "As discussed for anti- $\alpha 5\beta 1$  antibodies, a peptide that specifically binds  $\alpha 5\beta 1$  can be useful in a method of the invention where the antibody binds to  $\alpha 5\beta 1$  with at least about a two-fold greater specificity than it binds to another integrin, . . . is more useful if it has at least about a five-fold greater specificity for  $\alpha 5\beta 1$ , and is particularly useful if it has at least about a one order of magnitude greater specificity for  $\alpha 5\beta 1$  than for an integrin such as  $\alpha V\beta 3$ ."<sup>1</sup>

Based on this teaching, it is my understanding that Claim 2's term "**substantially**" refers to the exemplary preferred mathematical ranges (*i.e.*, at least about two-fold, five-fold, and ten-fold) for binding of the ligand (as exemplified by a peptide or antibody) to  $\alpha 5\beta 1$  integrin, as compared to binding of the ligand to another integrin. From this teaching, it is my understanding that Claim 2's recitation of an agent which "does not substantially interfere with the specific binding of a ligand to an integrin other than  $\alpha 5\beta 1$  integrin" means that the agent's interference with the specific binding of  $\alpha 5\beta 1$  integrin to a ligand is at least two-fold greater than the interference of the agent with the specific binding of another integrin to its cognate ligand.

5. Claims 80-86, 90-96, and 110-116 recite that the binding of an "agent" to  $\alpha 5\beta 1$  integrin is at least two-fold, five-fold, or ten-fold greater than binding of the agent to an integrin other than  $\alpha 5\beta 1$  integrin.

6. The Specification teaches that "As disclosed herein, antibody, peptide and nonpeptide small organic molecule antagonists of  $\alpha 5\beta 1$  can interfere with the specific binding of  $\alpha 5\beta 1$  integrin with its ligands, particularly fibronectin, in vascular tissue, and can reduce or inhibit angiogenesis (see Examples II, III and IV). Such molecules that interfere with the specific binding of  $\alpha 5\beta 1$  with its ligands are referred to herein generally as '*agents*.'"<sup>2</sup>

The Specification also teaches that "The term '*antagonist*' is used herein to mean an *agent*, which can be an antibody, a peptide or a nonpeptide small organic molecule."<sup>3</sup>

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<sup>1</sup> Specification, page 23, lines 5-14.

<sup>2</sup> (Emphasis added) Specification, page 18, lines 7-15.

<sup>3</sup> (Emphasis added) Specification, page 19, lines 24-27.

Based on these teachings, it is my understanding that the term "**agent**" of Claims 80-86, 90-96, and 110-116 is exemplified by an antibody, peptide, and/or nonpeptide small organic molecule.

7. The Specification teaches that "As discussed for anti- $\alpha 5\beta 1$  antibodies, a peptide that specifically binds  $\alpha 5\beta 1$  can be *useful* in a method of the invention where the antibody binds to  $\alpha 5\beta 1$  with at least about two-fold greater specificity than it binds to another integrin, . . . is more useful if it has at least about a five-fold greater specificity for  $\alpha 5\beta 1$ , and is particularly useful if it has at least about a one order of magnitude greater specificity for  $\alpha 5\beta 1$  than for an integrin such as  $\alpha V\beta 3$ ."<sup>4</sup>

Based on this teaching, it is my understanding that one property which makes an **antibody** or a **peptide** "useful" as an antagonist of  $\alpha 5\beta 1$  binding to its ligand(s) is that the antibody or peptide binds with at least about two-fold greater, at least about five-fold greater, or at least about ten-fold greater specificity for  $\alpha 5\beta 1$  than for  $\alpha V\beta 3$ . From this understanding in combination with my further understanding that an antibody and peptide are examples of an "agent," (as explained in item 6, *supra*), it is my opinion that the inventor contemplated that this desirable property (*i.e.*, relative binding to  $\alpha 5\beta 1$  as compared to  $\alpha V\beta 3$ ) which makes the exemplary antibodies and peptides "useful" in the claimed methods, is also a desirable property that is contemplated for **any other type of agent**, including the third exemplary type of nonpeptide small organic molecule. In other words, the Specification conveys to me that the inventor contemplated that one desirable property of **any agent** that interferes with the specific binding of  $\alpha 5\beta 1$  integrin to its ligand is that the agent (regardless of its type) binds with at least about a two-fold greater, at least about five-fold greater, or at least about ten-fold greater specificity for  $\alpha 5\beta 1$  than for  $\alpha V\beta 3$ .

8. Claims 86, 96, and 116 recite that an agent which interferes with specific binding of the  $\alpha 5\beta 1$  integrin to a ligand "does not interfere with the specific binding of a ligand to an integrin other than  $\alpha 5\beta 1$  integrin."

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<sup>4</sup> (Emphasis added) Specification, page 23, lines 5-14.

9. The Specification teaches that "Particularly useful antibodies for performing a method of the invention are those that specifically bind to an  $\alpha 5\beta 1$  integrin. Such antibodies are particularly useful where they bind  $\alpha 5\beta 1$  with at least an order of magnitude greater affinity than they bind another integrin, for example,  $\alpha V\beta 3$  or  $\alpha V\beta 5$ . An anti-fibronectin antibody also can be *useful* in a method of the invention, particularly an anti-fibronectin antibody that interferes with *binding* of fibronectin to  $\alpha 5\beta 1$  integrin, *but not to  $\alpha V\beta 3$  or other integrin.*"<sup>5</sup>

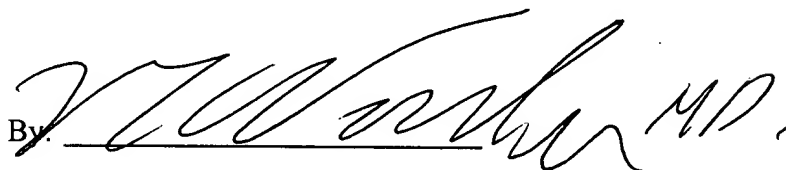
Based on this teaching, it is my understanding that one desirable property which makes an **antibody** "useful" in the claimed methods is that the antibody does not interfere with the specific binding of a ligand (such as fibronectin) to an integrin other than  $\alpha 5\beta 1$ . While this teaching refers to a desirable property of an antibody, it is nonetheless my opinion that this desirable property was contemplated by the inventor to apply to **any agent** because the Specification teaches that antibodies are an example of an agent (as explained *supra* in item 6).

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: \_\_\_\_\_

1/2/2002

By: \_\_\_\_\_

 MD.

Dr. Virgil L. Woods

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<sup>5</sup> (Emphasis added) Specification, page 22, lines 15-19.

## CURRICULUM VITAE

January 2, 2002

NAME: Virgil L. Woods, Jr., M.D.

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### PERSONAL AND FAMILY:

BIRTH DATE: July 8, 1948

BIRTH PLACE: Oakland, California

MARITAL STATUS: Married, three children

### EDUCATION:

1972 B.S., University of California, San Francisco, Major: Medical Sciences

1974 M.D., University of California, San Francisco, Major: Medicine

1979 B.A., University of California, San Diego, Major: Biochemistry

### PROFESSIONAL EXPERIENCE:

1974 - 1975 Intern in Medicine, Barnes Hospital, St. Louis, Missouri

1975 - 1976 Resident in Medicine, Barnes Hospital, St. Louis, Missouri

1976 - 1979 Research Associate, Laboratory of Immunology, NIAID-NIH, Bethesda, MD

1979 - 1981 Rheumatology Fellow, University of California, San Diego

1981 - 1988 Assistant Professor of Medicine In Residence, University of California, San Diego

1988 - 1989 Associate Professor of Medicine in Residence, University of California, San Diego

1989 - 1992 Associate Professor of Medicine, University of California, San Diego

1992 - Present Associate Professor of Medicine and Orthopaedics, University of California, San Diego

**MILITARY SERVICE:**

July 1977 to U.S. Public Health Service  
July 1979 Discharged with rank of Surgeon (Lt. Commander)

**MEDICAL SPECIALTY BOARDS:**

1978 American Board of Internal Medicine  
1991 Subspecialty Boards in Rheumatology

**FEDERAL GOVERNMENT PUBLIC ADVISORY COMMITTEES:**  
Grant Reviewer, Study Section for NIH NIAMD

**MEMBERSHIP IN PROFESSIONAL SOCIETIES:**

Member, American College of Rheumatology  
Member, Alpha Omega Alpha Medical Society  
Member, American Society of Hematology  
Member, American Heart Association, Council on Thrombosis  
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**REVIEWER FOR:**

Arthritis and Rheumatism  
Blood  
Journal of Biological Chemistry  
Protein Science  
Experimental Cell Research

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August 23-27, 1993.

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